INSTITUTIONAL REVIEW BOARD REVIEW CATEGORIES

A. Expedited Review

The IRB uses expedited review for activities which present no more than minimal risks to human participants and involve only procedures listed in one or more categories as authorized under 45 CFR 46.101 and 21 CFR 56.110 of the federal regulations. The inclusion of an activity among those which are eligible for expedited review does not mean that the activity only involves minimal risks, rather it only indicates that it is eligible for expedited review. In addition to the use of the expedited review process on those activities listed herein, the IRB also has the prerogative to use expedited review in considering minor changes in a previously approved activity.

The process cannot be used if revealing the identity of a participant in an activity would reasonably place that individual at risk of criminal or civil liability or damage the participant's financial standing, employability, eligibility for insurance, reputation, or stigmatize the individual **unless** reasonable and appropriate measures will be implemented by the principal investigator to render the risks associated with invasion of privacy and breach of confidentiality to a level no greater than minimal.

Use of the expedited review process by the IRB can only be employed in accordance with the mandate of the federal regulations. **It should not be perceived as a "hurry-up process."**

The categories of activity that meet the criteria for expedited review are:

1. Collection of blood sample by finger stick, heel stick, ear stick, or venipuncture;

a. For healthy, non-pregnant adults who weigh at least 110 pounds, the amounts drawn should not exceed 550 ml in an 8 week period and collection should not occur more frequently than 2 times per week; or

b. For other adults and children taking into consideration the age, weight and the health of the participant, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected, the amount drawn should not exceed the lesser of 50 ml or ml per kg in an 8 week period and collection should not occur more frequently than 2 times per week.

2. Prospective collection of biological specimens for research purposes by non-invasive means:

a. Hair and nail clippings, in a non-disfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.

b. Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

c. Recording of data from participants 18 years of age and older using no-invasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied to the surface of the body or at a distance and do not involve input matter or significant amounts of energy into the participant or invasion of the participant's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echocardiography, and electroretinography. It does not include exposure to electromagnetic radiation

outside the visible range (for example, x-rays, microwaves).

d. Collection of both supra- and sub-gingival plaque and calculus, provided the procedure is not more than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

e. Voice recordings made for research purposes such as investigations of speech defects.

f. Moderate exercise by healthy volunteers.

g. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

h. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate participants' behavior and the research will not involve stress to participants.

i. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

B. Exempt

Activities in which the only involvement of human participants will be in one or more of the categories stipulated in 45 CFR 46.101b will be given consideration for exemption by the IRB unless otherwise required by the DHHS, DOD or other federal agencies.

Determination of the exempt status of a project is the responsibility of the Howard University Institutional Review Board. Thus, all activities involving humans in any way must be submitted to the board for its review.

Exempt from coverage by the regulations are activities in which the only involvement of human participants will be in one or more of the following **six** categories:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, **unless**: (a) information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and (b) any disclosure of the human participants responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) (b) of this section, **if:** (a) the

human participants are elected or appointed public officials or candidates for public office; or (b) Federal statute (s) require (s) without exception that the confidentiality of personally identifiable **information** will be maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

5. Research and demonstration projects which are conducted by or participant to the approval of the university, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefit or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed or (b) if a food is consumed that contains a food ingredient at or below the level and use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.